Onset® (Onpharma) Project #12-007 (4/13)

Onpharma's Sodium Bicarbonate Injection, 8.4%, USP Neutralizing Additive Solution is a sterile, nonpyrogenic, solution of sodium bicarbonate ($NaHCO_3$) in water for injection. It is added to Lidocaine w/ Epinephrine as a neutralizing agent immediately prior to injection. This product is indicated to hasten the onset of analgesia and reduce injection pain by adjusting Lidocaine with Epinephrine anesthetic solution to a more physiologic pH immediately prior to injection. The solution cartridges, containing 1.7 mL volume are sold in a four-cartridge package. The Onset® Mixing Pen is a precision compounding and dispensing device used to mix two solutions together. Once assembled, the Pen enables the precise transfer of fluid from a standard 3 mL size cartridge into a second container, such as a 1.8 mL cartridge, allowing the two solutions to be mixed. Prior to use, the Onset® Mixing Pen is disassembled to its 2 parts, and a 3 mL size cartridge is inserted into the Cartridge Chamber (the Pen's housing). The pen is reassembled and a 2nd fluid container, such as a 1.8 mL cartridge, is attached to the end of the Pen. The Pen's volume dispensing dial is then turned so that the desired amount of solution can be transferred from the 3 mL size cartridge into the 2nd fluid container. Upon depressing the dispensing button, fluid is transferred from the 3 mL size cartridge into the 2nd fluid container allowing the two solutions to be mixed. The re-usable Onset® Mixing Pen is sold 1 per box and is provided non-sterile. The Onset® Cartridge Connector is used for the transfer of sterile solutions from one sealed container into a second sealed container and provides a reservoir for collecting excess solution displaced from the second sealed container during the transfer process. The Onset® Cartridge Connector may be used with the Onset® Mixing Pen. The Onset® Cartridge Connector has a sterile transfer tube that creates a fluid path between the two containers and is designed to allow the solution from the first container to be delivered via the transfer tube into the second container, where it mixes with the fluid in the second container. Simultaneously, fluid is displaced from the second container into the Fluid Reservoir. The Onset® Cartridge Connector is a sterile, disposable, device for transfer of fluids and collection of displaced fluids into a reservoir. The Onset® Cartridge Connector is supplied sterile, individually packaged, 4 per box.

Manufacturer:
Onpharma, Inc.
(877)336-6738,
(408)335-6850,
(408)335-1377, FAX,
www.onpharma.com

Suggested Retail Price:

Mixing pen	**$450.00**
1 Box sodium bicarbonate (4 ampules)	**$225.00**
1 Box of cartridge connectors (4)	**$50.00**
Shipping	**18.50**

Government Price:

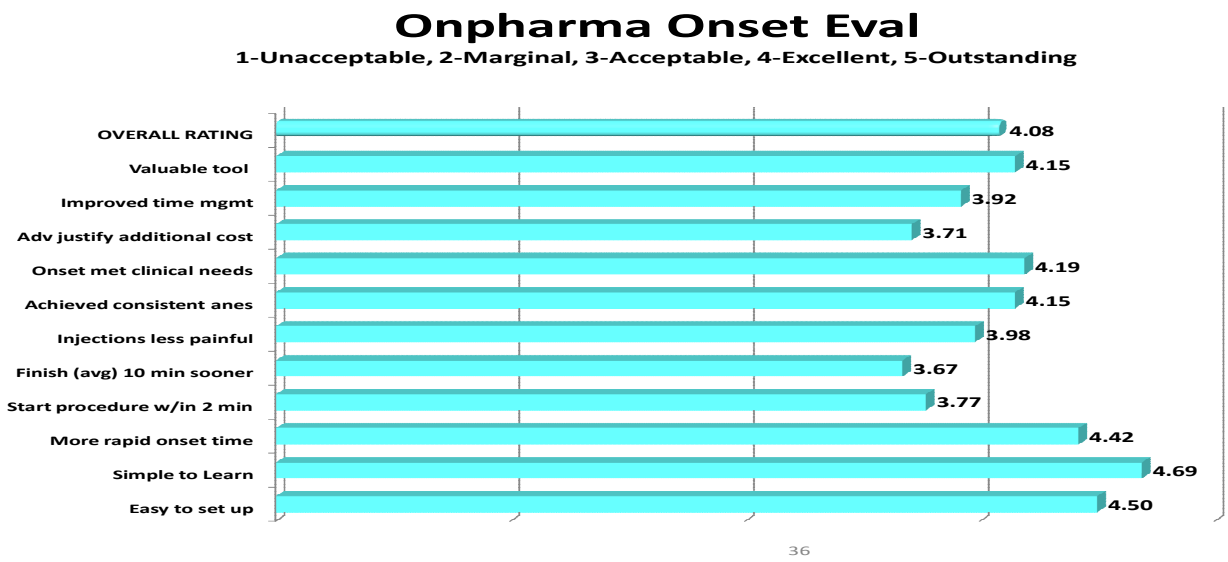
Mixing pen	**$225.00**
1 Box sodium bicarbonate (4 ampules)	**$175.00**
1 Box of cartridge connectors (4)	**$39.00**
Shipping	**$18.50**

ADVANTAGES:
+ Rapid onset, start procedure faster, reduced treatment time (20)
+ Less painful injections, improved patient comfort/experience (17)
+ Profound, consistent anesthesia (5)

+ Easy to use, (3)
+ Use with abscess, cellulitis (1)

DISADVANTAGES:
– Cost/Expense (13)
– Instability (6)
– Extra step (7)
– Waste (3)
– Technique Sensitivity (1)
– Infection control concerns (1)
– More bleeding issues (1)
– patients report more post op soreness at injection site (1)

SUMMARY AND CONCLUSIONS:
During the period of the survey, 26 evaluators completed 262 procedures. The vast majority of evaluators (25/26) felt the Onset® Mixing Pen was easy to set up and prepare for clinical use and (25/26) felt the chairside buffering process was simple to learn. The overwhelming majority (25/26) felt the onset time was more rapid when using buffered lidocaine, Seventy-three percent of evaluators (19/26) were able to start the procedure within two minutes and (14/26) felt they finished their procedures 10 minutes faster with the buffered anesthetic. A high number (21/26) felt they achieved consistent anesthesia with the buffered lidocaine. Eighty percent of evaluators felt the injections were less painful. A sizeable number (22/26) felt that buffering lidocaine was a valuable tool in dentistry and 23/26 felt it met their clinical needs. According to our questionnaire, fifty-eight percent of evaluators (15/26) felt that the advantages justified the added cost. The manufacturer stated (personal communication) that the additional cost was approximately five dollars per injection. Considering that most federal clinics operate from one dental chair, the extra ten minutes would certainly save chair time, and theoretically, money. But this assumes that scheduling can be performed in ten minute increments and that an extra patient can be seen during the day. It is beyond the scope of this evaluation to determine whether cost effectiveness can actually be proven. Scientifically, and in this evaluation, there seems to be little doubt that the product hastens anesthesia. Recently, Malamed et al[30] (Feb 2013) published a study that demonstrated significantly faster onset of anesthesia and reduced pain on injection with an alkalinized formulation of lidocaine with epinephrine. Ninety-six percent of evaluators said that they achieved faster mandibular anesthesia with Onset®, and eighty percent said that injections seemed to be less painful. Evaluators cited several advantages of buffering anesthetic to include rapid onset of anesthesia, less painful injections, profound/consistent anesthesia and an easy to use product.



Thirty-eight percent of evaluators reported having a problem using Onset®. One reported no profound anesthesia. Both the manufacturer and DECS want to make clear that Onset® cannot provide anesthesia when a clinician misses the block. Anesthesia must be administered in the proper location for any local anesthetic to work. The most common problem reported was that profound anesthesia was not achieved in two minutes. These evaluators questioned the profoundness of mandibular anesthesia in two minutes, but 96% of evaluators said that anesthesia was sufficient in four minutes, which is still faster than with no buffer. Others reported instability of the buffering solution with less effectiveness over time and one reported problems with assembly of the mixing pen. Disadvantages listed included added cost, instability and waste of unused of buffering solution, technique sensitivity, infection control concerns, one report of more bleeding issues in periodontal surgery and one report of post op soreness at the injection site. **Onset® (Onpharma)** chairside sodium bicarbonate buffering solution is rated **Excellent** for use in US Air Force dental facilities.